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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/579,403	05/12/2006	Mads Torry Smith	10561.204-US	1367

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EXAMINER
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MARX, IRENE

ART UNIT	PAPER NUMBER
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1651

MAIL DATE	DELIVERY MODE
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10/20/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/579,403	SMITH ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Irene Marx	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 16 July 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 7-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6, 13 and 14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/4/07, 5/12/06</u>  | 6) <input type="checkbox"/> Other: _____                          |

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### **DETAILED ACTION**

The application should be reviewed for errors.

To facilitate processing of papers at the U.S. Patent and Trademark Office, it is recommended that the Application Serial Number be inserted on every page of claims and/or of amendments filed.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Applicant's election with traverse of Group I, claims 1-6 on 7/16/08 is acknowledged. The traversal is on the ground(s) that because "the special technical feature shared by the instant inventions of groups I and II is a method for carrying out a fermentation process, wherein the method comprises adding said carbohydrate generating enzyme after the lag phase of the fermenting organism. However, this argument fails to take into account that the timing of "adding said carbohydrate generating enzyme after the lag phase of the fermenting organism" would depend not only on the nature of the "organism" fermented, but would also strongly depend on the nature of the specific culture medium provided for the organism. It is well known in the art that rich media result in practically no lag phase while synthetic media may result in a very long lag phase. Similarly, transfers from rich to poor media result in long lag phases. Applicant has failed to identify the correspondence between the lag phases between the two process. Therefore, no special technical feature is clearly identified that is shared by the addition of a broad class of enzymes at any time after the lag phase of processes of producing unidentified products with unidentified organisms in unidentified media.

For these reasons, the restriction requirement is deemed proper and is adhered to. The restriction requirement is hereby made FINAL.

Claims 1-6 and 13-14 are being considered on the merits. Claims 7-12 are withdrawn from consideration as directed to a non-elected invention.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 and 13-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague indefinite and confusing in that there is no clear correlation between the preamble directed to "subjecting liquefied mash to a carbohydrate-source generating enzyme" and the step (a) "fermentation medium". Is it or is it not "liquefied mash"? If so, it should be positively recited.

Moreover, it is unclear that any enzyme "generates" a "carbohydrate-source". It can reasonably be presumed that the enzyme substrate is a carbohydrate. The terminology used renders the claim confusing. Also the terminology "acid fungal alpha amylase" does not appear to be art recognized. Is acid-stable or acid-resistant intended? No new matter may be added.

Claim 6 is vague, indefinite and confusing in the recitation of "said fermentation step is part of a **simultaneous** saccharification and fermentation process", since a lag phase is required prior to enzyme addition and no clear carbon source is present prior to enzyme addition in this context.

Claim 4 is internally inconsistent and confusing in that the preamble requires glucoamylase or alpha amylase or mixtures thereof, while the body of the claim is directed to a mixture only. It is unclear what is intended.

If a ratio is intended in claims 4 and 13-14 it is recommended that this be positively recited. Moreover, the units intended to determine the respective amounts cannot be readily ascertained.

Claims 1-6 and 13-14 are incomplete in the absence of a recovery step for the product produced.

While there is no specific rule or statutory requirement which specifically addresses the need for a recovery step in a process of preparing a composition, it is clear from the record and

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would be expected from conventional preparation processes that the product must be isolated or recovered. Thus, the claims fail to particularly point out and distinctly claim the "complete" process since the recovery step is missing from the claims. The metes and bounds of the claimed process are therefore not clearly established or delineated.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 5-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Oda *et al.*.

The claims are directed to the production of any fermentation product with a microorganism in the presence of a carbohydrate-source generating enzyme added after the lag phase and producing a product.

Oda *et al.* teaches the production of a fermentation product with a microorganism in the presence of a carbohydrate-source generating enzyme added after the lag phase and producing a product. See, e.g., Table 1 and page 2, col. 2. The carbohydrate-source generating enzymes are clearly produced and added to the fermentation medium after the lag phase.

Claim 2 is included to the extent that exponential phase appears to be initiated after lag phase.

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Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oda *et al.* in view of Fujii *et al.*, Lantero *et al.*, Takeda *et al.*, and Yoshizumi *et al.*.

The claims are directed to the production of any fermentation product with a microorganism in the presence of a carbohydrate-source generating enzyme added after the lag phase and producing a product.

Each of Oda *et al.*, Fujii *et al.*, Lantero *et al.*, Takeda., and Yoshizumi *et al.* disclose the production of a fermentation product by culturing a microorganism in the presence of a carbohydrate-source generating enzyme such as amylase. See, e.g., Oda *et al.* page 2, col. 2; Fujii *et al.*, page 54, col. 1; Lantero *et al.*, col. 4, lines 57-69; Takeda, col. 5; Yoshizumi *et al.*, Example 2. At least in Oda *et al.*, the carbohydrate-source generating enzymes are clearly produced and added to the fermentation medium after the lag phase.

The references differ from the claimed invention in that the timing of the addition of the carbohydrate source generating enzyme is not particularly indicated and in the ratio between the enzymes added. However, one of ordinary skill in the art would have recognized at the time the claimed invention was made that the timing of enzyme addition would depend on the extent of the lag phase. It is clear that the lag phase depends not only on the organism fermented but also on the process conditions, such as the fermentation media, as well as on the product desired to be produced. Therefore, one of ordinary skill in the art would have had a reasonable expectation of success in adding enzymes at some point after the lag phase, e.g., during the production phase of the process, in order to maintain the fermentation at its maximal yield and avoid possible glucose inhibition, for example.

In addition Lantero *et al.* disclose the use of various fungal alpha-amylases as well as their use mixed with glucoamylase in various amounts (See, e.g., bridging paragraph between col. 2 and 3.)

The process conditions and products discussed in the references appear to be substantially the same as claimed. However, even if they are not, the adjustment of process conditions for optimization purposes identified as result-effective variables cited in the references would have been prima facie obvious to a person having ordinary skill in the art, since such adjustment is at the essence of biotechnical engineering.

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Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the process of production of a fermentation product with a microorganism in the presence of a carbohydrate-source generating enzyme as disclosed by Oda *et al.*, Fujii *et al.*, Lantero *et al.*, Takeda., and Yoshizumi *et al.* by adding a carbohydrate-source generating enzymes such as acid fungal alpha amylase and glucoamylase after the lag phase of the fermenting organism in order to maximize the production of fermentable sugar for the expected benefit of maximizing the yield of valuable products such as ethanol and lactic acid from grains and other vegetable biomass containing starch, for example.

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 .

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Irene Marx/  
Primary Examiner  
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